

Applicant: Milton B. Maxwell, Jr.  
Serial No.: 10/686,900  
Filed: October 16, 2003  
Group Art Unit: 3626  
Attorney's Docket No.: N9461  
Customer No.: 23456

### **REMARKS**

This Application was filed with 28 claims. Claim 20 has previously been canceled. Claims 29-31 have previously been added. Claims 1-19 and 21-31 have been rejected. Claims 1 and 2 have been amended. Therefore, Claims 1-19 and 21-31 are pending in the Application. Reconsideration of the Application based on the remaining claims as amended and arguments submitted below is respectfully requested.

### **Claim Rejections - 35 U.S.C. § 103**

Claims 1-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Goetz et al. (U.S. Pat. No. 6,421,650) in view of Hacker (U.S. Pat. No. 6,988,075), further in view of Mayaud (U.S. Pat. No. 7,072,840).

### **Claim 1**

Claim 1 has previously been amended to include the steps of “identifying at least one disease the patient may have based on the medication specific data” and “generating one or more disease/drug contra-indications based upon relationships between the at least one disease and the medication specific data.” The Office Action states that these steps are included within a method taught by Mayaud.

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Applicant asserts that the method of Mayaud does not comport with that of the present Application. The Application is intended to identify potential diseases based on information specific to the medication, and without reference in this context to previously documented patient conditions or user-selectable options. *See* Application, ¶ 42. In other words, the system is free to identify each potential disease based on reliable data and without undue influence by users. The following step thereby generates a more complete list of disease/drug contra-indications than would be generated if the list of diseases were selectively limited.

In contrast, Mayaud specifically calls for user-selectable conditions. Mayaud generally intends to provide procedures for the user to select a drug most appropriate to a given condition, and to specify the condition being treated within a prescription management system so as to trace the efficacy of the treatment.

Mayaud provides a physician with a selective listing of drugs by conditions for which they have a therapeutic effect, accessible in real time. *See* column 5, line 55 through column 6, line 12. This citation does not identify potential conditions based on the medications, but performs the opposite function.

Mayaud also under the heading "Condition Selection" allows for conditions to be selected under different columns of subcategories of conditions, as a preliminary to drug listing or organization. *See* column 35, lines 21-37. This serves as a powerful tool to physicians in viewing and organizing prescribing options for a

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particular condition, but does not serve identify conditions based upon the medication prescribed.

Mayaud further under the heading "Direct Drug Selection" permits a physician to select a given drug and subsequently select from a list of conditions that the user/physician has previously treated with that drug and entered into the system. The user may alternatively view conditions that were entered into the system because the patient has previously been treated with the same drug. If the physician wants to use the selected drug to treat a condition outside of that which was previously entered, he or she must select the condition from a generic list. *See* column 38, line 35 through column 39, line 7. This citation does not allow for a comprehensive generation of contra-indications based upon the medication specific data. Rather, Mayaud reviews a completed prescription for contra-indications with regards to the specific one or more conditions cited therein. *See* column 31, lines 33-47 and column 32, lines 29-36).

Claim 1 has been amended to further clarify the distinctions between Mayaud and the present Application. Accordingly, the Applicant respectfully requests that the rejection to Claim 1 be withdrawn.

The Office Action states that the step of Claim 2 (Currently Amended) is taught by Goetz. Applicant has amended Claim 2 to more clearly articulate one of the claimed inventive features that distinguish Goetz in this case. Specifically,

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Claim 2 has been amended in part to state step (h) "... includes the step of facilitating the display of the side effect of the medication ~~which~~if it is severe and probable ..."

Goetz clearly fails to place any explicit limits upon the side effects to be displayed. In fact, Goetz explicitly teaches that side effects are not to be identified automatically from the database, but instead manually entered by a physician user or selected from a drop menu of options that were previously manually entered in the same fashion. See column 11, lines 8-17 and Figs. 19, 20. Goetz does not mention the severity of side effects at all. Severity with regards to drug-drug interactions is flagged, but there is no mention of limiting the display of such interactions based upon severity, and in any case this is irrelevant to Claim 2.

Claim 2 is further dependent back to patentably distinct Amended Claim 1. Accordingly, Applicant respectfully requests that the rejection to Claim 2 as currently amended be withdrawn.

Claims 3-7 are likewise dependent back to patentably distinct Amended Claim 1. As such, without further argument as to included features not disclosed in the prior art Applicant nevertheless respectfully submits that Claims 3-7 are patentable.

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### Claim 8

Applicant has previously amended Claim 8 to more clearly articulate inventive features. Specifically, Claim 8 was amended, in part, to state “comparing the patient’s medication information to a drug-drug interaction database to identify severe, moderate, and mild drug-drug interactions” and “compiling in the data system the identified severe and moderate drug-drug interactions, wherein the identified mild drug-drug interactions are suppressed.” See Application, ¶ 44.

The language regarding the suppression of mild interactions clearly distinguishes Goetz, which explicitly teaches that all drug-drug interactions should be displayed, both to a third party user such as a healthcare provider and the patient. Specifically, Goetz states

Similarly, a check of potential interactions and cautions concerning a particular prescription is performed in the pharmacist component 106. If an interaction is detected by the physician or pharmacist software, it warns the pharmacist or physician of the severity of the interaction. The interaction check in the pharmacist's computer and in the physician's component 102 serves a watchdog function only. The pharmacist or physician have the ability to override the software warning and prescribe the drug anyway. This is routinely done by physicians today for minor potential interactions when substitute drugs are either unavailable or would cause even more severe interactions. In either case, the interaction is flagged in the patient component 104 such that the patient can review the interaction warning thus alerting the patient that there is an interaction potential between two drugs. The patient is then able to read about the interaction,

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usually in a brief form, and consult the physician or pharmacist for more information if clarifications are needed. *See* U.S. Pat. No 6,421,650, Col. 12, lines 1-19.

As such, Goetz advocates that drug-drug interactions should be displayed to the patient, regardless of severity or whether or not the physician chooses to ignore the severity rating and prescribe the drug anyway. Rather than implicitly permitting mild interactions to be suppressed at the physician's option, Goetz explicitly states that all interactions remain for the patient to view. Goetz later partially explains why mild interactions are explicitly not to be suppressed, as "[T]he concurrent use of these medications together can result in severe illness or death." *See* column 15, lines 32-45. Regardless of the validity of the reasoning behind this decision, the method is clearly contrary to that stated in Claim 8 as previously amended. Accordingly, Applicant respectfully requests that the rejection to Claim 8 be withdrawn.

Claims 9-14 and 29 are dependent back to patentably distinct Previously Presented Claim 8, and include features not disclosed in the prior art. As such, Applicant respectfully submits that Claims 9-14 and 29 are patentable as well.

### Claim 15

Step (b) of Claim 15 was also previously amended "... to identify profile information, wherein the profile information excludes mild drug-drug interactions."

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As previously argued, excluding mild drug-drug interactions from the profile information is not taught or even suggested as being desirable by Goetz. Moreover, as shown in the arguments proffered in regard to Previously Presented Claim 8, Goetz discloses that drug-drug interactions of all severities should be displayed to the user. *See* '650, Col. 12, lines 1-19. Accordingly, the Applicant respectfully requests that the rejection to Claim 15 be withdrawn.

Claims 16-17 and 30 are dependent back to patentably distinct Previously Presented Claim 15, and in many cases include similar exclusions of mild drug-drug interactions or other features not disclosed in the prior art. As such, Applicant respectfully submits that Claims 16-17 and 30 are patentable.

#### Claim 18

Claim 18 was previously amended to include the step of "generating profile information, wherein the profile information excludes the medication side effects that are mild." As argued in greater detail above, Goetz shows that excluding side effects of medication that are classified as mild from patient profile information is not taught or even suggested as being desirable. Accordingly, the Applicant respectfully requests that the rejection to Claim 18 be withdrawn.

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Claims 19, 21, and 22 are dependent back to patentability distinct Previously Presented Claim 18, and include other features not disclosed in the prior art. As such, Applicant respectfully submits that Claims 19, 21, and 22 are patentable.

### Claim 23

Claim 23 was previously amended to include within the claimed profile “consequential information including identification of any drug-drug interactions of the prescribed medications, wherein the any identified drug-drug interactions having a severity classification of less than moderate are suppressed.” The same arguments presented in the discussion of Previously Presented Claim 8 regarding suppression of mild drug-drug interactions, or those that are less than moderate in severity, are also applicable to Previously Presented Claim 23. Accordingly, the Applicant respectfully requests that the rejection to Claim 23 be withdrawn.

Claims 24- 28 and 31 are dependent back to patentably distinct Previously Presented Claim 23, and include features not disclosed in the prior art. As such, Applicant respectfully submits that Claims 24-28 and 31 are patentable.

Applicant has commented on some of the distinctions between the cited references and the claims to facilitate a better understanding of the present invention. This discussion is not exhaustive of the facets of the invention, and Applicant hereby reserves the right to present additional distinctions as

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appropriate. Furthermore, while these remarks may employ shortened, more specific, or variant descriptions of some of the claim language, Applicant respectfully notes that these remarks are not to be used to create implied limitations in the claims and only the actual wording of the claims should be considered against these references.

Respectfully submitted,

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